

November 12, 2004

Susan J. Walker, M.D., Director,
Division of Dietary Supplement Programs (HFS-810),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
Department of Health & Human Services
5100 Paint Branch Parkway,
College Park, MD 20740

NOV 30 2004

Re: Your Letter of Oct. 28, 2004 - Regarding Structure/Function Statements

Dear Dr. Walker,

This is in response to your letter of October 28, 2004. Thank you for your valuable response on the proposed structure and function claims for "Aller-Bye".

We have taken the following actions based on your response:


1. The name "Aller-Bye" will not be used as the product name since it has been concluded by your office that the name implies that the product is intended to treat, prevent or mitigate diseases such as allergies.
2. The following structure and function claims will not be used for the product in accordance with your letter:
 - "Inhibits histamine production by mast cells"
 - "Supports the immune system's natural inflammatory response"
 - "Modulates the immune system for a healthy inflammatory response. The inflammatory response is the natural response of the immune system against any attack by foreign elements"
3. We have decided to use the other structure and function claims that were mentioned in my letter of October 12, 2004 that you had no objection to.

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We would also like to inform you that we have not launched the product as of yet. It is important for us as a company to ensure that all of our Structure Function Claims meet DSHEA regulations. Thank you for your guidance as it will help us to work better in compliance with both DSHEA and FDA guidelines.

Sincerely yours,



Amha Belay, Ph.D.
Senior Vice President/Scientific Director

Enclosure

October 12, 2004

Susan J. Walker, M.D., Director,
Division of Dietary Supplement Programs (HFS-810),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
Department of Health & Human Services
5100 Paint Branch Parkway,
College Park, MD 20740

OCT 18 2004

Re: Notification of Structure/Function Statements – Aller-Bye®

Dear Dr. Walker,

As per 21 CFR section 101.93, this letter is a notification of new structure/function claims to be made on labels, brochures and collateral materials of the following Earthrise Nutritionals dietary supplement: Aller-Bye®. The structure-function statements are listed on the enclosed attachment.

Manufacturer/Packer/Distributor: Earthrise Nutritionals, Inc.

The firm believes it has substantiation, and the structure-function claims are appropriate, truthful and not misleading. If you have any questions or concerns, please do not hesitate to contact me at (760) 348-5027 extension 21.

Sincerely yours,



Amha Belay, Ph.D.
Senior Vice President/Scientific Director

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Enclosure

October 12, 2004

Structure/Function Statements For Earthrise Nutritionals, Inc.
Aller-Bye® Dietary Supplement

OCT 18 2004

Aller-Bye®: (Capsule)

Ingredients: Earthrise® Spirulina Gold® (*Spirulina (Arthrospira) platensis*) and Vitamin C.

i) Immune & Respiratory Health Structure/Function Statements

- Supports respiratory health*
- Supports healthy immune system, sinus and respiratory tract.*
- Earthrise® Aller-Bye® : a natural Spirulina-based, proprietary product which supports the immune system.*
- A clinical study shows that Earthrise Aller-Bye® balances the immune system naturally. Further studies show that Spirulina supports healthy respiratory function.*

ii) Immunomodulation Structure/Function Statements

- Earthrise® Aller-Bye® modulates the immune system by supporting normal IL-4 levels.*
- Earthrise® Aller-Bye® is a Spirulina-based proprietary blend which modulates the immune system by supporting healthy IgE levels.
- Inhibits IgE production.*

-Earthrise® Aller-Bye® is a Spirulina-based proprietary blend which inhibits histamine production by mast cells.*

-The ratio/balance of two types of immune T-helper cells (called Th₁ and Th₂) is important for healthy immune function. Earthrise® Aller-Bye® provides immune health by supporting a healthy ratio/balance of Th₁ and Th₂ cells.*

iii) Immune & Inflammatory Response Structure/Function Statements

-Earthrise® Aller-Bye® is a natural Spirulina based proprietary product that is clinically shown to support the immune system's natural inflammatory response.*

-Studies have shown that Earthrise® Aller-Bye® modulates the immune system for a healthy inflammatory response. The inflammatory response is the natural response of the immune system against any attack by foreign elements. Reports from clinical studies also suggest that this Spirulina based product supports a healthy respiratory function.*

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(The disclaimer appears in the appropriate places on labels and brochures).

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